



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review, 30-day Comment Request: Certificate of Confidentiality

Electronic Application System

SUMMARY: Under the provisions of Section 3507(a) (1)(D) of the Paperwork Reduction Act of 1995, the Office of Extramural Research (OER), National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on April 29, 2013, page 2590 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of Extramural Research (OER), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-

6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project contact: Dr. Ann Hardy, NIH Extramural Human Research Protections Officer and NIH Coordinator, Certificates of Confidentiality, 3701 Rockledge Dr, Rm. 3002, Bethesda, MD 20892, or call non-toll-free number (301) 435-2690 or E-mail your request, including your address to: hardyan@od.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Certificate of Confidentiality Electronic Application System, 0925-New, Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: This application system will provide one electronic form to be used by all research organizations that wish to request a Certificate of Confidentiality (CoC) from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. §241(d)), CoCs are issued by the agencies of Department of Health and Human Services (DHHS), including NIH, to authorize researchers conducting sensitive research to protect the

privacy of human research subjects by enabling them to refuse to release names and identifying characteristics of subjects to anyone not connected with the research. At NIH, the issuance of CoCs has been delegated to the individual NIH Institutes and Centers (ICs). The NIH ICs collectively issue approximately 1000 new CoCs each year for eligible research projects. However, the process for submitting a CoC request is not consistent across the ICs which creates confusion for applicants. To make the application process consistent across the entire agency, OER is proposing to use an electronic application system that will be accessed by research organizations that wish to request a CoC from any NIH IC. Having one system for all CoC applications to NIH will be efficient for both applicants and NIH staff who process these requests. As is currently done, NIH will use the information in the application to determine eligibility for a CoC and to issue the CoC to the requesting organization.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,500.

Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response	Annual Hour Burden
CoC Applicants-Private	400	1	90/60	600
CoC Applicants-State/local	450	1	90/60	675
CoC Applicants-Small business	50	1	90/60	75
CoC Applicants-Federal	100	1	90/60	150

Dated: November 13, 2013

Seleda Perryman

Chief, Project Clearance Officer

Office of Policy for Extramural Research Administration

National Institutes of Health

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